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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/337,675 06/22/99 JAIN

R 029318/0497

FOLEY & LARDNER  
3000 K STREET, SUITE 500  
WASHINGTON DC 20007-5109

HM12/1129

EXAMINER

PULLIAM, A

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

11/29/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/337,375

Applicant(s)

PECHHOLD ET AL.

Examiner

Amy E Pulliam

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 June 1999.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 1999 is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 14) ☒ Notice of References Cited (PTO-892)
- 15) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 16) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 17) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 18) ☐ Notice of Informal Patent Application (PTO-152)
- 19) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of the Preliminary Amendment, submitted June 22, 1999.

#### ***Drawings***

The drawings are objected to because of reasons specified on the attached PTO 948. Correction is required.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruddy et al. Ruddy et al disclose a longer acting pharmaceutical composition, comprising nanoparticles of a therapeutic agent with a surface modifier adsorbed on the surface, and a method of treating mammals using the said composition. Ruddy et al further disclose that the surface modifier can be selected from pharmaceutically known organic and inorganic excipients, including polymers and surfactants (col 2, lines 50-55). The preferred surface modifier in Ruddy et al's invention is HPMC (col 2, line 48), and its concentration by weight in the composition can be between 0.1 and 90%,

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preferably 1-75%, and most preferably 20-60% (col 5, lines 56-58). Ruddy et al also disclose that the preferred average particle size of the nanoparticles is less than 400 nm (col 5, line 65). Ruddy et al also allow for the inclusion of excipients, binders and lubricants, such as magnesium stearate (col 10, paragraph 3). Lastly, Ruddy et al's disclosure teaches oral administration of the composition, in all of the forms well known in the pharmaceutical art, such as tablet and capsule form (col 10, line 53), and further allows for the coating of the composition (col 10, line 55). Ruddy et al does not teach the specific concentrations of the excipients present in the composition, nor do they teach of all the specific types of formulations. However, based on the general teaching of the presence of excipients, and the teaching that Ruddy's composition can be formulated into any form well known in the pharmaceutical art, it is the position of the examiner that the specific concentrations, and forms of the composition are limitations that would be routinely determined by one of ordinary skill in the art through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected result. Those results must be those that accrue from the specific limitations. Further, it is the position of the examiner that the teaching of HPMC in the composition reads on applicant's claim to both a surface stabilizer and a rate controlling polymer, because on page 12, line 27-28, applicant states that a suitable surface stabilizer includes various polymers.

### ***Conclusion***

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy Pulliam, whose telephone number is (703) 308-4710. The examiner can normally be reached Monday to Friday from 7:30 am to 4:00 pm.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist whose telephone number is (703) 308-1234.

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600